REMARKS/ARGUMENTS

Claims 1 – 6 remain in this application. Claim 2 has been canceled. Claim 1 has been amended. Claims 7-43 have been withdrawn. A three-month extension request has been filed along with this response.

Dependent claim 2 has been incorporated into claim 1 to better define the invention. Support for this amendment may be found on page 8, last paragraph of the specification.

35 USC 102 Rejections

Claims 1 and 6 have been rejected under 35 U.S.C.102(b) as being anticipated by Sasaki Kazuyuki et al. The Sasaki reference teaches the administration of a combination of glutamine and glicentin for the treatment of digestive disorders such as ulcerative or inflammatory digestive tract diseases, digestive tract damage caused by digestive tract removal, radiation or parenteral nutrition. For the Examiners review, we have attached a translation of this reference from the JPO web site. The Applicants would like to direct the Examiner to table 1, which describes the effect of different medicine on the ileal mucous membrane mass of rats. The five groups tested were a 1) untreated control, 2) glicentin, 3) glutamine, 4) combination of glicentin and glutamine and 5) MTX treated control. The data shows that the group administered the combination of glicentin and glutamine had ileal mucous weight similar to the untreated control and that the glicentin or glutamine treatments had ileal mucous weights similar to the MTX treated control, i.e. no effect. Similar results are documented in table 2 for the jejunal mucous membrane, which is the glutamine treatment had no effect. Similar trends are found in table 3 and 4, which describe the DNA content of the ileal and jejunum respectively. The administration of a combination of glicentin and glutamine resulted in a remarkable high DNA value while the DNA level for glicentin or glutamine treated rats resulted in DNA values similar to the MTX treated control, i.e. no effect. In summary, the Sasaki Kazuyuki et al patent application teaches that glutamine is not effective at treating digestive disorders such as ulcerative or inflammatory digestive tract diseases, digestive tract damage caused by digestive tract removal and radiation or

parenteral nutrition. Therefore, this reference teaches away from the use of glutamine. The Applicant's request that the rejections based upon this reference be withdrawn.

Claims 1-3 and 6 have been rejected under 35 U.S.C. 102(b) as being anticipated by Kihlberg et al. The Kihlberg patent teaches a method of parenterally administering N-acetyl L-glutamine separately, sequentially or simultaneously with medium chain fatty acids and/or a growth factor. The key word here is parenterally. The Kihlberg patent references intravenously and injected administration throughout the specification (column 4, lines 4-9, 21, 30 and Example 1 line13, Example 2 line 42 and Example lines 23-24). Nowhere is enteral or oral administration suggested in the Kihlberg patent. Parenteral administration of NAQ is consistent with the prior art. Palmerini et al. orally administered radio-labeled N-acetyl-L- glutamine to rats. "Uptake of Doubly-Labeled N-Acetyl-L-Glutamine in Rat Brain and Intestinal Mucosa *In Vivo*, *Farmaco*, vol. 36(7), pp. 347-355 (July 1981) and demonstrated that N-acetyl L-glutamine (NAG) was absorbed intact across the intestinal mucosa. The lack of intestinal hydrolysis of the acetyl function leads one skilled in the art to discount NAG as a potential source of glutamine in nutritional products, since one of glutamine's primary activities is to nourish gut epithelium. This function occurs predominantly during the intestinal absorption of the amino acid.

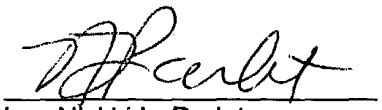
As discussed in the summary of the instant application, the Applicant's discovered that N-acetyl L-glutamine has utility as an oral glutamine supplement in humans. The Applicant's have discovered that human intestinal tissue can deacetylate N-acetyl L-glutamine. Therefore, N-acetyl-L-glutamine can be incorporated into liquid nutritionals designed for human consumption. These compositions possess long-term stability and provide the N-actetyl-L-glutamine in a form that is bioavailable for humans. Claim 1 specifically requires oral administration of NAQ. The Applicant's request that the rejections based upon this reference be withdrawn.

35 USC 103 Rejection

Claims 1-6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kihlberg et al in view of Crawford. As discussed above, Kihlberg teaches a method of parenterally administering N-acetyl L-glutamine separately, sequentially or simultaneously with medium chain fatty acids and/or a growth factor. Crawford teaches that it is well-known in the art to utilize the aluminum salts of NAQ to prevent the exacerbation of gastric ulcers in rats. This reference suggests that aluminum salts of NAQ are utilized in the stomachs of rats to treat ulcers. It does not speak to the bioavailability of NAQ salts in the intestine, or the deacetlyation of NAQ salts by the intestine to nourish the intestinal epithelium. The teachings of Crawford does not address the deficiencies of Kihlberg et al., that is oral vs. parenteral delivery of NAQ to nourish and support the intestinal mucosa. One knowledgeable in the art wound not be motivated by Crawford in light of Palmerini et al to orally administer aluminum salts of NAQ to humans to prevent disease of the intestinal mucosa. The Applicant's request that the rejections based upon these references be withdrawn.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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